

## **REMARKS**

### **I. Status of the Application**

Claims 1-21 are presently pending in the application. Claims 6-8, 10 and 21 stand objected to as being in improper form. Claims 2, 4, 10-14 and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 20 and 21 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,685,957. Claims 1-13, 20 and 21 stand rejected under 35 U.S.C. § 102(a) as being anticipated by WO 01/10478. Claims 1-7 and 9-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Goedemoed et al. (U.S. Patent No. 5,980,948). Claims 1-14 stand rejected under 35 U.S.C. § 103(a) as obvious over Goedemoed et al. (U.S. Patent No. 5,980,948) in view of WO 01/10478 or Bakker et al. (U.S. 2002/0095213 A). Claims 1-7, 9-14, 20 and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bakker et al. (U.S. Patent No. 5,480,436). Claims 1-14, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as obvious over Bakker et al. (U.S. Patent No. 5,480,436) in view of WO 01/10478 or Bakker et al. (U.S. 2002/0095213 A). Claims 1-9, 12-15 and 17-21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Bakker et al. (U.S. 2002/0095213 A). Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as obvious over Bakker et al. (U.S. 2002/0095213 A) in view of Bakker et al. (U.S. Patent No. 5,480,436), Goedemoed et al. (U.S. Patent No. 5,980,948), WO 01/10478 or EP 0 830 859. Claims 1-14, 20 and 21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Bezemer et al. (U.S. Patent No. 6,685,957).

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, claim 1 has been amended as to form and in response

to the concerns about preamble limitation to clarify the claimed invention as the combination of a medical device and an advantageous coating. Claim 1 has been further amended to include limitations of claim 8 for the average molecular weight of the copolymer, the limitations of claims 9-11 for the biologically active additive, and the limitations of claim 12 for the surface material. Accordingly, claims 8, 9 and 12 have been cancelled. Support for the amendments can be found on page 1, paragraphs 1 and 7 of the specification, where Applicants describe the invention as relating to a coating (for medical devices) comprising a copolymer of a polyalkylene glycol terephthalate and an aromatic polyester. Support for the molecular weight limitations can be found on page 2, lines 27-29. Support for the additive limitations can be found from page 6, line 26 to page 15, line 5. Support for the surface limitations can be found on page 5, lines 11-21. Claims 1-4, 6-7, 10-11, 13, 15 and 21 have been amended to correct formal matters. Claim 14 has been amended to claim a coating which is porous upon application to the surface. Support for this amendment can be found on page 16, lines 18-23, which describes agents used to form said porous coating. New claims 22-26 have been added to claim certain ranges. Support for these amendments can be found on page 2, lines 18-21, 24-25 and 27-29, page 5, lines 26-30, and page 6, lines 1-2.

Thus, the amendments presented herein add no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

## **II. Claims 2, 4, 10, 11, 13, 14 and 21 Are Definite**

On page 2, lines 7-9 of the instant Office Action, claims 2, 4, 10-14 and 21 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner is of the opinion that these claims fail to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection based on the amended claims now presented. Claims 2, 4, 10, 11, 13 and 21 have been amended to recite proper Markush language. Claim 1 has been amended to claim an apparatus comprising a medical device and a coating on the surface of the medical device, further defined by the described copolymer with biologically active additive, as well as the described surfaces. In light of claim 1, which is now directed to a coating applied to a surface, claim 14 has been amended to specify that the coating is porous after application to the surface. Page 16, lines 18-23 of the specification teaches that in order to form a porous coating (after application to a surface), one should add a pore-forming agent to the copolymer before application. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections based on 35 U.S.C. § 112, second paragraph and allow claims 2, 4, 10, 11, 13, 14 and 21.

## **III. Claims 20 and 21 Are Novel over Bezemer et al. (U.S. Patent No. 6,685,957).**

On page 3, lines 16-21 of the instant Office Action, claims 20 and 21 stand rejected under obvious-type double patenting as being unpatentable over claims 6 and 7 of Bezemer et al. (U.S. Patent No. 6,685,957). The Examiner is of the opinion that claims 20 and 21 are not patentably distinct from claims 6 and 7 of Bezemer et al. because the instant coating has little probative value absent further limitation, and the instant medical device encompasses the implant of said

patent. Applicants respectfully traverse this rejection based on the amended claims now presented.

Amended claim 1, on which claims 20 and 21 depend, is directed to a medical device having a coating applied to the surface of the medical device. Claim 1 of Bezemer et al., on which claims 6 and 7 depend, is directed to a process for preparing a **polymer fiber which is shaped into an implant**. Applicants' claimed copolymer coating requires that it be applied to a surface as disclosed in claim 1. Bezemer et al. is directed to a different embodiment, namely an implant formed from polymer fibers. Applicants respectfully submit that the claimed medical device including the claimed coating is not obvious over an implant formed from polymer fibers made by the wet spinning technique. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection based on obviousness-type double patenting and allow claims 20 and 21.

**IV. Claims 1-13, 20 and 21 Are Novel over WO 01/10478.**

On page 4, lines 10-11 of the instant Office Action, claims 1-13, 20 and 21 stand rejected under 35 U.S.C. § 102(a) as anticipated by WO 01/10478. The Examiner is of the opinion that WO 01/10478 teaches the copolymer of claims 1-6, the molecular weights of claims 7 and 8 (now amended into claim 1), the incorporation of biologically active agents of claims 9-11 (now amended into claim 1), and the medical devices of claims 20 and 21. Applicants respectfully traverse this rejection based on the amended claims now presented.

Amended claim 1, on which claims 2-13, 20 and 21 depend, is directed to a medical device having a coating on a defined surface. WO 01/10478 is directed to a process for preparing a **solid body of polymer by gel molding**. The disclosed copolymer gel of WO

01/10478 can be injection molded or spun into a fiber (page 16, lines 14-28), but WO 01/10478 does not teach or suggest that the copolymer gel can be used to coat a surface of a medical device. Therefore, WO 01/10478 fails to teach or suggest each and every element of claim 1. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection based on 35 U.S.C. § 102(a) and allow independent claim 1 and dependant claims 2-13, 20 and 21.

**V. Claims 1-7, 10, 11, 13 and 14 Are Novel over Goedemoed et al.**

On page 4, lines 21-22 of the instant Office Action, claims 1-7 and 9-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by Goedemoed et al. (U.S. Patent No. 5,980,948). The Examiner is of the opinion that Goedemoed et al. teaches the copolymer of claims 1-6, the molecular weights of claim 7, the incorporation of biologically active agents of claims 9-11 (now amended into claim 1), the coated medical devices of claim 13, and the porous coating of claim 14. Applicants respectfully traverse this rejection based on the amended claims now presented.

Amended claim 1, on which claims 2-7, 10, 11, 13 and 14 depend, is directed to a medical device having a coating on the surface of the medical device. Goedemoed et al. is directed to a biologically active agent encapsulated in a **microsphere comprising a polyetherester copolymer**. Goedemoed et al. does not teach or suggest that the disclosed microspheres can be used to coat a surface of a medical device as claimed. Also, the Examiner admits that Goedemoed et al. does not specify the molecular weight range of copolymer recited in amended claim 1. Therefore, Goedemoed et al. fails to teach or suggest each and every element of independent claim 1 and dependant claims 2-7, 10, 11, 13 and 14. Accordingly,

Applicants respectfully request that the Examiner withdraw the rejection based on 35 U.S.C. § 102(b) and allow claims 1-7, 10, 11, 13 and 14.

**VI. Claims 1-14 Are Not Obvious over Goedemoed et al. in View of WO 01/10478 or Bakker et al. (U.S. 2002/0095213 A).**

On page 5, lines 8-9 of the instant Office Action, claims 1-14 stand rejected under 35 U.S.C. § 103(a) as obvious over Goedemoed et al. (U.S. Patent No. 5,980,948) in view of WO 01/10478 or Bakker et al. (U.S. 2002/0095213 A). The Examiner is of the opinion that it would be obvious to one of ordinary skill in the art to utilize the polyethylene glycols with molecular weights disclosed in Goedemoed et al. to synthesize copolymers with molecular weights disclosed by WO 01/10478 or Bakker et al. Applicants respectfully traverse this rejection based on the amended claims now presented.

Amended claim 1, on which claims 2-14 depend, is directed to a medical device having a coating, the coating being characterized by a copolymer of a polyalkylene glycol terephthalate and an aromatic polyester, wherein the weight average molecular weight of the copolymer is between about 10,000 and about 300,000, the coating further comprising a biologically active agent, and the surface being selected from the group consisting of metals, metal alloys, ceramics, glasses, and polymeric materials. As discussed above, both Goedemoed (microspheres) and WO 01/10478 (gel molded copolymer bodies) fail to teach or suggest all of Applicants' claim limitations, namely a medical device having a coating as claimed.

Goedemoed et al. is directed to copolymer microspheres, while Bakker et al. is directed to various prosthetic devices made from the copolymer. Neither of these references suggests the desirability of combining their teachings to arrive at the claimed subject matter. One skilled in the art would find no motivation to use polyethylene glycol with molecular weights of

Goedemoed et al. to synthesize copolymer with molecular weights of Bakker et al. in order to produce the copolymer coating in claim 1.

There are many problems in designing coatings for medical devices. One of the bigger problems concerns the adhesion of the coating to the material of which the medical device is made. Often, coatings do not adhere well to different kinds of materials. Since many different materials are used in the manufacture of medical devices, it is important that the coating material has good adhesion to a wide range of different materials (page 1, lines 12-17 of the specification).

The adhesion of the coating material must not only be good in ambient conditions, but with respect to certain medical devices also *in vivo*. The environment around the medical device during use can be completely different from ambient conditions, which can cause the medical device to deform. The coating should be able to withstand such deformations without breaking or coming loose (page 1, lines 18-24).

At the time of invention, it was believed that biocompatible polymer coatings did not sufficiently adhere to a wide range of different materials. The skilled person wanting to prepare a coating for a medical device would thus not be motivated to use prior art biocompatible copolymers as coating materials for medical devices.

The present invention surprisingly shows that copolymers of polyalkylene glycol terephthalate and aromatic polyester can be adjusted so as to provide good adhesion to nearly any type of material (page 2, lines 5-8). In addition, the elastic behavior of the biocompatible copolymers provides enough flexibility to withstand deformations of the medical device without breaking or coming loose (page 5, lines 8-10). The cited references simply would not have led the skilled person in the direction of the present invention. Applicants respectfully request that

the Examiner withdraw the rejection based on 35 U.S.C. § 103(a) and allow independent claim 1 and dependant claims 2-14.

**VII. Claims 1-7, 10, 11, 13, 14, 20 and 21 Are Novel over Bakker et al.**

On page 6, lines 1-2 of the instant Office Action, claims 1-7, 9-14, 20 and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Bakker et al. (U.S. Patent No. 5,480,436). The Examiner is of the opinion that Bakker et al. teaches the copolymer of claims 1-6, the molecular weights of claim 7, the incorporation of biologically active agents of claims 9-11 (now amended into claim 1), the coated medical devices of claims 13, 20 and 21, and the porous coating of claim 14. Applicants respectfully traverse this rejection based on the amended claims now presented.

Amended claim 1, on which claims 2-7, 10, 11, 13, 14, 20 and 21 depend, is directed to a medical device having a coating applied to the surface of a medical device, the coating being characterized by a copolymer of a polyalkylene glycol terephthalate and an aromatic polyester, wherein the **weight average molecular weight of the copolymer is between about 10,000 and about 300,000**. The Examiner has admitted that Bakker et al. does not specify a molecular weight range for the disclosed copolymers. Bakker et al. also does not disclose the inclusion of biologically active agents in the copolymer (salt particles as pore-forming agents are not included as biologically active agents described in amended claim 1). Therefore, Bakker et al. fails to teach or suggest each and every element of claim 1. Applicants respectfully request that the Examiner withdraw the rejection based on 35 U.S.C. § 102(b) and allow independent claim 1 and dependant claims 2-7, 10, 11, 13, 14, 20 and 21.



**VIII. Claims 1-14, 20 and 21 Are Not Obvious over Bakker et al. (U.S. Patent No. 5,480,436) in View of WO 01/10478 or Bakker et al. (U.S. 2002/0095213 A).**

On page 6, lines 11-13 of the instant Office Action, claims 1-14, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as obvious over Bakker et al. (U.S. Patent No. 5,480,436) in view of WO 01/10478 or Bakker et al. (U.S. 2002/0095213 A). The Examiner is of the opinion that it would be obvious to one of ordinary skill in the art to utilize the polyethylene glycols with molecular weights disclosed in Bakker et al. (US '436) to synthesize copolymers with molecular weights disclosed by WO 01/10478 or Bakker et al. (US '213). Applicants respectfully traverse this rejection based on the amended claims now presented. The problems associated with prior art coatings or lack thereof is described above.

Amended claim 1, on which claims 2-14, 20 and 21 depend, is directed to a medical device having a coating applied to the surface of a medical device, the coating being characterized by a copolymer of a polyalkylene glycol terephthalate and an aromatic polyester, wherein the weight average molecular weight of the copolymer lies between about 10,000 and about 300,000, and the surface being selected from the group consisting of metals, metal alloys, ceramics, glasses, and polymeric materials. Bakker et al. (US '436) is directed to copolymer bilayers, while WO 01/10478 is directed to gel-molded copolymer solid bodies. Neither of these references provides motivation to combine their teachings on molecular weights in order to obtain the invention, a copolymer coating applied to the surface of a medical device, because neither reference suggests that such a combination would provide a copolymer with good adhesion to the variety of surfaces described in claim 1. Bakker et al. (US '436) only discloses a device comprising a copolymer coated on another layer of copolymer, but not on metals, ceramics, or glasses.

Bakker et al. (US '436) is directed to copolymer bilayers, while Bakker et al. (US '213) is directed to various prosthetic devices made from the copolymer. Neither of these references suggests the desirability of combining their teachings to arrive at the claimed subject matter. One skilled in the art would find no motivation to use polyethylene glycol with molecular weight of Bakker et al. (US '436) to synthesize copolymer with molecular weight of Bakker et al. (US '213) in order to produce the copolymer coating in claim 1.

Lacking the requisite motivation to combine the references, Applicants respectfully request that the Examiner withdraw the rejection based on 35 U.S.C. § 103(a) and allow independent claim 1 and dependant claims 2-14, 20 and 21.

**IX. Claims 1-7, 13-15 and 17-21 Are Novel, or in the Alternative, Not Obvious over Bakker et al. (U.S. 2002/0095213 A).**

On page 7, lines 6-8 of the instant Office Action, claims 1-9, 12-15, and 17-21 stand rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Bakker et al. (U.S. 2002/0095213 A). The Examiner is of the opinion that Bakker et al. teaches the copolymer of claims 1-6, the molecular weights of claims 7 and 8 (now amended into claim 1), the additive of claim 9, the copolymer applied to the surfaces of claim 12, the medical devices of claims 13, 20 and 21, the porous coating of claim 14, and the methods of coating application of claims 15 and 17-19, or that the claims are obvious in light of Bakker's disclosure. Applicants respectfully traverse this rejection based on the amended claims now presented.

Applicants note that claim 10 reciting a biologically active agent has not been similarly rejected. Accordingly, Applicants have amended claim 1 to include a biologically active agent.

Accordingly, Applicants respectfully request that the Examiner withdraw the rejections based on 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) and allow claims 1-7, 13-15 and 17-21.

**X. Claims 1-21 Are Not Obvious over Bakker et al. (U.S. 2002/0095213 A) in View of Bakker et al. (U.S. Patent No. 5,480,436), Goedemoed et al., WO 01/10478 or EP 0 830 859.**

On page 7, lines 20-22 of the instant Office Action, claims 1-21 stand rejected under 35 U.S.C. § 103(a) as obvious over Bakker et al. (U.S. 2002/0095213 A) in view of Bakker et al. (U.S. Patent No. 5,480,436), Goedemoed et al. (U.S. Patent No. 5,980,948), WO 01/10478 or EP 0 830 859. The Examiner is of the opinion that it would be obvious to one of ordinary skill in the art to combine the coating of Bakker et al. (US '213) with the copolymer incorporating biologically active agents of Bakker et al. (US '436), Goedemoed et al., WO 01/10478, and EP 0 830 859. The Examiner is also of the opinion that it would be obvious to clean the surface of the substrate before applying coating because doing so is routine practice in the art. Applicants respectfully traverse this rejection based on the amended claims now presented.

The Examiner has not provided any evidence on which to base the conclusion that cleaning the substrate surface before applying a coating is routine practice in the art. None of the cited references disclose a process for coating application which includes cleaning of the substrate surface and the Examiner cannot use the Applicants' disclosure in hindsight reconstruction.

The skilled artisan would not be motivated to combine Bakker et al. (US '213) with Bakker et al. (US '436), Goedemoed et al., WO 01/10478, and EP 0 830 859 to arrive at the claimed subject matter because Bakker et al. teaches deposition of calcium on or into the polymer *in vivo*, the opposite of releasing an additive already incorporated in the polymer.

Bakker et al. (US '213) does not suggest that its polymer coating, upon which calcium is deposited *in vivo*, can also be used to release biologically active agents. Therefore, claims 1-21 are not obvious over Bakker et al. (US '213) in view of Bakker et al. (US '436), Goedemoed et al., WO 01/10478 or EP 0 830 859. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections based on 35 U.S.C. § 103(a) and allow claims 1-21.

**XI. Claims 1-14, 20 and 21 Are Novel over Bezemer et al.**

On page 8, lines 17-18 of the instant Office Action, claims 1-14, 20 and 21 stand rejected under 35 U.S.C. § 102(e) as anticipated by Bezemer et al. (U.S. Patent No. 6,685,957). The Examiner is of the opinion that Bezemer et al. teaches the copolymer of claims 1-6, the molecular weights of claims 7 and 8 (now amended into claim 1), and the incorporation of biologically active agents of claims 9-11 (now amended into claim 1). Applicants respectfully traverse this rejection based on the amended claims now presented.

Amended claim 1, on which claims 2-14, 20 and 21 depend, is directed to a medical device having a coating on the surface of the medical device as claimed. Bezemer et al. is directed to a process for preparing a **polymer fiber which is shaped into an implant**. Bezemer et al. does not teach or suggest that the disclosed copolymer emulsion can be used to coat a surface. Nor does it disclose a coating of copolymer applied to one of the surfaces as defined in claim 1. Bezemer does not teach all of Applicants' claim limitations and accordingly, Applicants respectfully request that the Examiner withdraw the rejection based on 35 U.S.C. § 102(e) and allow claims 1-14, 20 and 21.

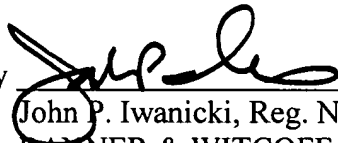
## **XII. CONCLUSION**

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

Dated: February 21, 2006

By



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